

REMARKS

Claims 7, 24, 25 and 26 will be presently pending and under consideration upon entry of this amendment. Claims 7 and 25 have been amended in order to more clearly claim the invention described in the specification. In particular, claim 7 has been amended to recite a method to increase production of at least one Th1 cytokine or to decrease production of at least one Th2 cytokine, comprising administering to a human an effective amount of a peptide to increase production of at least one Th1 cytokine or to decrease production of at least one Th2 cytokine, said peptide consisting of the amino acid sequence Cys Lys Pro Ile Ser Gly His Asn Ser Leu Phe Trp Tyr Arg Gln Thr (SEQ ID NO:1), and which human is free of infection with an immunodeficiency-type retrovirus.

Additionally, claim 25 has been amended to remove reference to “immunoglobulin G.” Accordingly, claim 26 has been added in view of the amendment to claim 25. Claim 26 is fully supported in the specification, *e.g.*, at page 4, lines 10-32 and page 14, lines 27-28.

No new matter is added by the amendments to the claims.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 7 and 25 are rejected under 35 U.S.C. § 112, second paragraph, allegedly, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicants regard as the invention. In particular, the Examiner states that claim 7 is vague for failing to specify the scientific objective of increasing Th1 or decreasing Th2 cytokine levels. Further, the Examiner states that claim 25 is vague for reciting immunoglobulin G, which is not a cytokine.

Applicants respectfully disagree with the Examiner. The “distinctly claim” requirement of 35 U.S.C. § 112, second paragraph, means that the claims must have a clear and definite meaning when construed in light of the complete patent document. Standard Oil

Co. v. American Cyanamide Co., 774 F.2d 448, 227 USPQ 293 (Fed. Cir. 1985). The test of definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Orthokinetics, Inc. v. Safety Travel Chairs, Inc. 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). A claim need not describe the invention, such description being provided by the specification's disclosure section. Id. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986).

Claim 7 relates to using an effective amount of a particular peptide in order to increase production of at least one Th1 cytokine or to decrease at least one Th2 cytokine. The specification clearly teaches that increasing Th1 cytokines or decreasing Th2 cytokines maintains proper immune system functioning, *i.e.*, proper amounts and ratios of cytokine production in the presence of an underlying pathogenic condition. Such pathogenic conditions include, but are not limited to, immune dysfunction and cytokine dysregulation, HIV infection, AIDS, cardiovascular system diseases and disorders, allergic diseases or disorders, cancer, infection with a viral, bacterial or fungal agent. Applicants submit that the claims, when read in light of the specification, reasonably apprise those skilled in the art of the claimed invention, *i.e.*, that those skilled in the art clearly understand the scientific objective of increasing Th1 cytokines or decreasing Th2 cytokines.

Regarding the rejection of claim 25, Applicants have amended claim 25 such that immunoglobulin G is no longer recited as a Th2 cytokine. However, Applicants accordingly have added new claim 26, which recites a method to increase production of at least one Th1 cytokine or to decrease production of immunoglobulin G, comprising administering to a human an effective amount of a peptide to increase production of at least one Th1 cytokine or to decrease production of immunoglobulin G, said peptide consisting of the amino acid sequence Cys Lys Pro Ile Ser Gly His Asn Ser Leu Phe Trp Tyr Arg Gln Thr

(SEQ ID NO:1), and which human is free of infection with an immunodeficiency-type retrovirus.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the rejections under 35 U.S.C. § 112, second paragraph, have been overcome. Thus, Applicants respectfully request withdrawal of these rejections.

CONCLUSION

Applicants respectfully request that the above-made remarks of the present response be entered and made of record in the file history present application.

Applicants request that the Examiner call the undersigned at (212) 326-3921 if any questions or issues remain.

Respectfully submitted,

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